

June 24, 2013

**By Electronic Filing**

Michael E. Gans  
Clerk of the Court  
United States Court of Appeals for the Eighth Circuit  
Thomas F. Eagleton U.S. Courthouse  
111 South 10th Street  
St. Louis, Missouri 63102

Re: United States ex rel. Laurie Simpson v. Bayer Healthcare, et al., No. 12-2979  
Response concerning Bayer's Response to Appellant's 28(j) Letter

Dear Mr. Gans:

Bayer's arguments, going well beyond Simpson's 28(j) letter, are wrong. Simpson respectfully responds to Bayer's several points.

The Government took care in its most recent Statement to explain that the Medicare statutory scheme is merely "one way" in which the Government regards claims as "non-reimbursable." The Government did not explain other "ways," such as those that Simpson sets forth in both that case and this one, where it did not need to do so to show that Bayer's motion to dismiss should fail. Simpson alleges with particularity that (for example) Bayer's misconduct rendered Baycol illegal for distribution in interstate commerce. The Court may safely (and certainly plausibly) conclude, under the standard noted below, that claims for reimbursement for such drugs are "non-reimbursable."

Simpson's allegations compel (and easily permit) the inference that the doctors who were receiving kickbacks prescribed Baycol as a result of the kickbacks, where (for example) Bayer's internal analysis concluded that through the program by which the kickbacks were made, Bayer had substantially increased the percentage of doctors who were prescribing Baycol. (A113-14 ¶ 219.)

This Court has no bright-line rule requiring a relator to allege specific examples of false claims no matter the context. The recent Statement explains how and why that makes sense. Simpson's allegations compel (and easily permit) the inference that claims for reimbursement for Baycol were submitted. Bayer still does not dispute otherwise.

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Bayer's argument regarding the appropriate materiality standard presupposes that only by citing a statute or regulation expressly identifying claims as "non-reimbursable" may a relator allege materiality with "particularity." No case so holds, and as noted at the outset of this letter, the Government has just explained that the argument is incorrect. This Court clearly regards Rule 8 "plausibility" as informing Rule 9(b), reducing the inquiry regarding materiality to whether it is plausible that the Government would regard the claims for reimbursement as "non-reimbursable": Vigil clearly explains (at 798), including by reference to Hawley, that the relator must "allege facts creating plausible inferences" that the allegedly false claims at issue "were presented to the government and were material to its payment decisions."

Respectfully submitted,

/s/ Edward Normand  
Edward Normand

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